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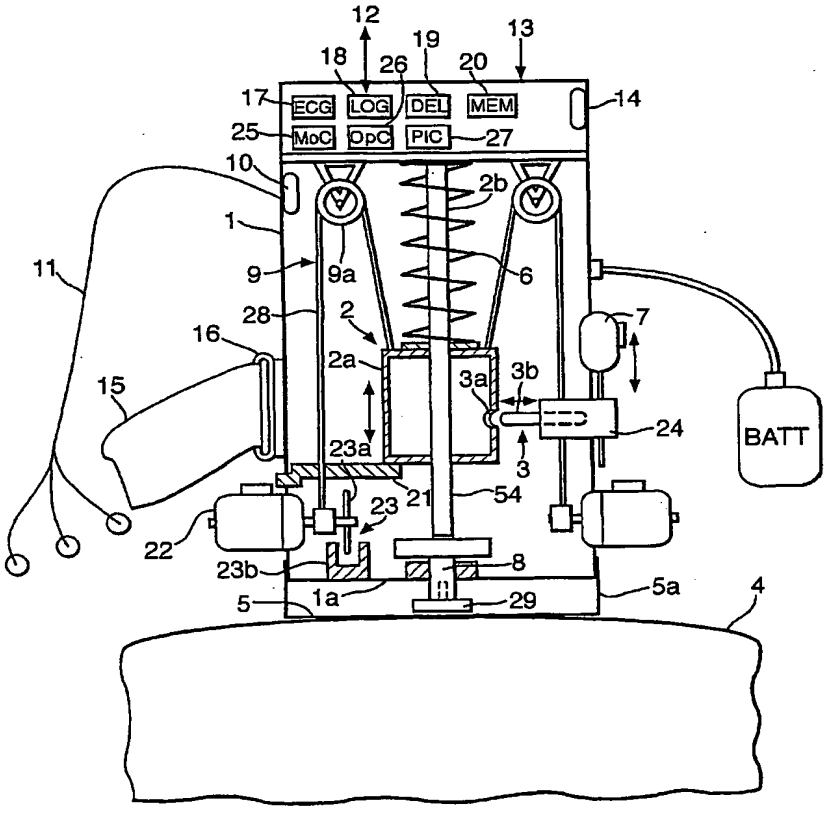
(54) Title: EXTERNAL MECHANICAL CARDIAC STIMULATOR



(57) Abstract: A cardiac stimulation device for treating dysrhythmia of the heart of a patient has a housing (1) for disposition on the chest of the patient (4) having an impact mechanism including a plunger arrangement (2) arranged to deliver an external impact to the chest of the patient (4) with an energy capable of stimulating electrical excitation and subsequent contraction of the heart of the patient. The device has circuitry to cause controlled operation of the impact mechanism. An ECG signal representative of the cardiac rhythm is recorded and analysed, to output a trigger signal indicative of a need for stimulation of the heart, which is used to trigger a mechanical impact. The device may operate during brady and tachy-cardic dysrhtyhmias, including asystole, ventricular tachycardia or fibrillation. It offers an advantageous alternative to electrical simulation of the heart, in particular requiring lower energies which cause less trauma to the patient and increases portablility.

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External Mechanical Cardiac Stimulator

The present invention relates to the treatment of cardiac dysrhythmias, that is abnormal rhythmicity of heartbeats. In particular, the present invention relates to a device capable of stimulating the heart by mechanical means to perform such treatment.

By way of a simple classification, cardiac dysrhythmias may be divided into two classes. The first class is bradycardias, which includes those dysrhythmias in which the heart beats too slow. Asystole, that is the absence of a regular heart beat, may be thought of as an extreme bradycardia. The second class is tachycardias, which includes those dysrhythmias in which the heart beats too fast. For the purpose of this classification, fibrillation is regarded as an extreme form of tachycardia, in which there is ill-coordinated contraction of individual cardiac muscle fibres, resulting in the lack of effective contraction of cardiac chambers. Ventricular fibrillation (VF) is fatal unless promptly terminated by conversion to rhythmic and coordinated contraction of myocardium (cardioversion).

A number of techniques and devices are known for treating dysrhythmias. The most common form of treatment is by electrical stimulation. Normal cardiac contraction is activated by the intrinsic electrical activity of the heart, and disturbances in the normal sequence of electrical activation of the heart can lead to dysrhythmias. Extrinsic electrical stimulation of the heart may give rise to such disturbances (electrocution). Conversely, controlled electrical stimulation can be used to treat various dysrhythmias (e.g. external electrical defibrillation).

Several types of device for providing controlled electrical stimulation are known. Implantable pacemakers, and more recently implantable cardioverters/ defibrillators (ICDs), have been applied with great success in preventing sudden cardiac death from dysrhythmias. These devices continuously monitor the cardiac rhythm and provide controlled electrical stimulation directly to the heart on detecting an dysrhythmia. ICDs are capable of detecting and treating a wide range of dysrhythmias. For example, they may treat bradycardia by providing extra electrical stimulation to initiate rhythmic cardiac contractions (commonly known as pacing).

Similarly, life-threatening ventricular tachycardia (VT) and fibrillation may be treated by applying controlled electrical stimulation to reinstate normal cardiac rhythm (cardioversion or defibrillation).

Another common device for treatment of cardiac dysrhythmias by controlled electrical stimulation is the external electrical defibrillator. Such a device applies a high voltage electric shock through electrodes applied externally to the chest of a patient. It is used to treat life-threatening ventricular dysrhythmias, in particular fibrillation, by electrically terminating the dysrhythmic activity and allowing normal cardiac rhythm to recommence.

External defibrillators require the application of relatively high electrical energies because of i) the need to capture the electrical activity of a sufficiently large proportion of myocardium, while ii) much of the applied electrical stimulus dissipates to areas other than the target organ (causing, for example, activation of large proportions of skeletal muscle). Typical energy levels required for external electrical defibrillation are of between 2 and 4 joules per kilogram of body weight, and leading to typical applied energies in the order of 200 joules and above.

Sustained lack of cardiac activity and circulation causes death. Measures to re-institute normal cardiac activity must therefore be applied with minimal delay. A known manual technique for extending the period of time during which successful cardioversion may be performed is cardiac massage. This involves rhythmic application of pressure on the thorax to compress the heart to maintain basic levels of circulation. The manual pressure deforms the thorax and underlying tissues, including the heart. This directly drives blood from the heart into the arteries. External cardiac massage is applied in a smooth, rhythmic manner at a rate of the same order as a normal cardiac rhythm. The technique places a high mechanical burden on both the patient and the person applying the treatment, yet provides a comparatively small cardiac output; the blood volume ejected from the heart, even of optimally performed external cardiac massage, is limited to about one quarter to one third of normal ventricular ejection. Such external cardiac massage is a standard part of cardiopulmonary resuscitation (CPR) and has been one of the most successful

medical interventions in emergency medicine. Mechanical devices for assisting CPR are available, generally designed to replace human specialists and avoid fatigue during the application of cardiac massage.

According to the present invention, there is provided a cardiac mechanical stimulation device for treating dysrhythmia of the heart of a patient, comprising: a housing for disposition in a precordial position on the chest of the patient, having an impact mechanism arranged to deliver an external mechanical stimulus to the chest with mechanical properties capable of stimulating contraction of the heart of bradycardiac patients (mechanical pacing), or terminating dysrhythmias, including VF, in tachycardic patients (mechanical cardioversion/defibrillation); a cardiac monitor comprising an intervention determination circuit arranged to monitor an ECG signal representative of the rhythm of the heart of the patient and output a trigger signal indicative of a need for mechanical stimulation of the heart and providing the timing information for the impact; a control circuit arranged to cause operation of the impact mechanism for controlled mechanical stimulation in response to the trigger signal output by the intervention determination circuit.

The present invention provides a device for treating cardiac dysrhythmias by providing external mechanical stimulation. In particular, the device may deliver an external impact to the chest of the patient. The mechanical stimulation has mechanical characteristics capable of stimulating additional contractions of the heart of bradycardiac patients (mechanical pacing), or terminating dysrhythmias, including VF, in tachycardic patients (mechanical cardioversion/defibrillation). For example, the impact mechanism may be arranged to deliver an external impact having a duration of at most 100ms or preferably at most 10ms, typically of the order of 1ms. As discussed in more detail below with reference to treating specific dysrhythmias, the device uses the principle that a mechanical impact may be used to affect cardiac electrical excitation and stimulate competent contraction of the myocardium. It is thought that this results from the intra-cardiac relationship between mechanical and electrical stimulation of the heart, so that a mechanical impact results in an effect similar to that of an electrical shock. In particular, this contrasts with the application

of mechanical compression during cardiac massage in which force is applied over a period which is relatively long (compared to the here-proposed external mechanical stimulation) to externally cause ejection of blood from the passive, non-contracting cardiac chambers.

The device also includes a cardiac monitor which comprises an intervention determination circuit. This is a standard component of contemporary ICD technology which may be applied to the cardiac stimulation device of the present invention. The cardiac monitor may further include an ECG detection system to produce the ECG signal representative of the cardiac rhythm, or this may be externally provided to the device. It may further include an output circuit which may be used to allow external monitoring of the ECG. The intervention determination circuit monitors the ECG signal and outputs a trigger signal indicative of the timing for cardiac stimulation needed. A control circuit is arranged to cause operation of the impact mechanism in response to the trigger signal. Therefore, it is straightforward to implement the control circuit for the mechanical stimulation provided by the present invention by applying a cardiac monitor of a type which is known and approved for use in ICDs.

Devices in accordance with the present invention may be arranged to treat several types of dysrhythmia. In each case, this may be achieved by arranging the intervention determination circuit to output a trigger signal on detection of the particular dysrhythmia. This is in itself conventional in the cardiac monitors of known ICDs although for triggering electrical stimulation rather than mechanical stimulation (the principal difference being the delivery of energy in a different form).

Firstly, a device in accordance with the present invention may be used to treat VT. It is expected that the device will be effective for such treatment, because of the known effectiveness of a manually applied chest thump. In particular, it has been known for several decades that a single thump to the precordial chest may be effective for reverting VT, for example by evoking a premature beat that interrupts the tachycardia-sustaining re-entry pathway.

The timely use of mechanical stimulation by a device in accordance with the present invention is expected to be particularly advantageous as a preventative

measure, since it is know that lethal dysrhythmias such as VF are preceded by VT in about 90% of cases. For example, currently there are between 250,000 and 300,000 cardiac arrests annual in the United States, and about 80,000 to 100,000 in each of the United Kingdom and Germany. These are currently being treated predominantly by CPR and electrical defibrillation. Depending to a large extent on the delay between the onset of the cardiac dysrhythmia and the application of resuscitatory measures, such treatment restores spontaneous circulation in around 40% to 60% of arrests. Consequently, use of the device in accordance with the present invention to prevent VT from deteriorating into VF by performing early mechanical cardioversion, has the potential of reducing the incidence of fatal cardiac arrests.

An international survey currently being performed by the inventor and his team shows a difference in the clinical utility of manually applied chest thump between the US and the United Kingdom, with the success rate in the US being about three-fold higher than in the UK. The reasons for this discrepancy are still under investigation, but early data (reporting on over 1,200 cases of precordial thump) show that US medical personnel rank VT as their prime indication for application of chest thump, whereas in the focus in the UK is on VF. The higher success rate in the US serves to emphasise the desirability of applying mechanical cardioversion during the early development of serious dysrhythmias.

Manually applied chest thumping for reversal of witnessed cardiac arrest is an accepted emergency procedure. For example, the US International Liaison Committee on Resuscitation (ILCOR) recommended "Basic life support (BLS) should be performed until advance life support (ALS) becomes available. In the event of a monitored arrest, a precordial thump is considered a class I recommendation by the ILCOR. For an unwitnessed (onset of the) arrest and in children, the thump is a class IIb recommendation". This is similar to the current guidelines of the United Kingdom Resuscitation Council. In recent years, manual precordial thump has, however, been de-emphasised, in part because of the large variability in outcome. This is caused by the inability of i) exactly controlling impact energy and ii) optimally timing manually applied impacts. The device in accordance

with the present invention would of course apply a controlled impact at the desired moment relative to the cardiac cycle, as identified by the cardiac monitor.

For treatment of the VT, it is expected that the impact mechanism should be arranged to deliver an impact with an energy of from 1 to 10 joules, preferably from 3 to 8 joules. The actual energy required is expected to depend on the patient in a similar manner that the energy applied during electrical cardioversion depends on the patient, and include parameters such as weight, physique, age and type of arrhythmia.

Secondly, a device in accordance with the present invention may be arranged to treat VF, particularly in an early stage of VF. It is expected that the device in accordance with the present invention will be of use for treating such an dysrhythmia, because there are reported cases of success reversal of VF by a chest thump, although such cases are relatively rare. In all the reported cases, the mechanical stimulation was applied very early in the development of VF, either at the verge of deterioration of VT into VF or within the first 5 to 15 seconds after the onset of VF, as verified by ECG and occasionally arterial pressure recordings. Thus the device in accordance with the present invention has the potential of terminating at least early VF.

For treatment of VF, it is expected that the impact mechanism should be arranged to deliver an impact with an energy of from 1.5 to 15 joules, preferably from 4 to 12 joules, or more preferably from 6 to 10 joules. The actual energy required is expected to depend on the patient, in a similar manner that the energy applied during electrical cardioversion depends on the patient, and include parameters such as weight, physique, age and type of arrhythmia. Thus for the treatment of VT, and possibly also VF, the device in accordance with the present invention may be used as an alternative to an external electrical cardioversion device.

Also, the device in accordance with the present invention may be used as a temporary alternative to an ICD or an additional safeguard against a malfunctioning ICD.

Thirdly, a device in accordance with the present invention may be applied to treat bradycardia and asystole. In this regime of operation, the device is an alternative to an electrical pacemaker. The device provides mechanical stimulation

to regulate, or pace the cardiac rhythm. It is thought that the device of the present invention will be effective for treatment of such dysrhythmias, because it has been known for at least eighty years that manually applied precordial percussion (repeated application of precordial thumps at a rate similar to the normal heartbeat) is effective to maintain blood flow in asystole. In particular, it has been shown that rhythmic thumps applied manually to the chest of patients in ventricular standstill have the potential of initiating single beats or runs of ventricular contraction. Such mechanically triggered cardiac contractions have a greater haemodynamic effect than external compression applied during cardiac massage, for example during CPR, and have been used to maintain consciousness in patients during periods of ventricular standstill caused by a Stokes-Adams syndrome. In one case, this method has been applied in a patient intermittently over more than 90 minutes to sustain reasonable levels of circulation and consciousness.

For the treatment of bradycardia, it is expected that the impact mechanism should be arranged to deliver an impact with an energy of between 0.01 to 5 joules, preferably 0.01 to 1 joules. The actual energy is expected to depend on the patient, for example on parameters such as weight, physique, age and type of dysrhythmia.

Therefore, it is expected that the device in accordance with the present invention could be used to perform such precordial percussion and thus be capable of maintaining circulation by eliciting ventricular contraction in the asystolic heart. On the basis of such cases during asystole and the use of electrical stimulation to regulate cardiac rhythm during bradycardia, it is expected that the device in accordance with the present invention will similarly be effective to pace cardiac rhythm during malignant bradycardia.

The preferred energy ranges quoted above for the different cardiac dysrhythmias have been ascertained through a series of tests based on manual thumps applied by medical personnel to simulate the thump they would apply to a patient. Thus the preferred energy ranges are expected to be the most effective ranges for treatment, but they are not limitative of the invention.

Although the precise mechanisms underlying mechanical effects on the

cardiac rhythm are not entirely understood, it is believed to be as follows. In general, diastolic stretch depolarises resting cardiac cells and tissues. This may be accounted for by mechanical operation of stretch-activated ion channels the cell membranes of cardiac cells, which would explain why stretch-induced reactions can also be seen in heart transplant recipients, isolated hearts and tissues, or even isolated cardiac cells. A popular illustration of these intra-cardiac effects on mechanical stimulation is the observation that volume pulses of sufficient amplitude, that is fluid injection into a left ventricular balloon, may "pace" an otherwise quiescent ventricle in an isolated, that is denervated, Langendorff rabbit heart preparation. The depolarising effect of stretch on resting cardiac tissue explains these clinical observations, because the mechanical stimulation depolarises resting myocardial tissue towards threshold for excitation and triggers contraction. During asystole or bradycardia, well timed mechanically-induced extra beats may be used to cause effective ventricular contraction to maintain circulation. Mechanical cardioversion of VT or early VF is a more complex phenomenon, but one possible mechanism is that supra-threshold mechanically-induced excitation of the resting proportions of myocardium interrupts the pathway for dysrhythmic excitation by synchronously cardiac excitation in large areas of the heart, subsequently rendering the myocardium non-excitable and thereby terminating certain types of the dysrhtyhmia (such as re-entrant electrical activity, for example).

A device may be arranged to treat a single type of dysrhythmia. More preferably, a device may be applied to treat any combination of different types of dysrhythmia, for example any two or more of the types of dysrhythmia referred to above, particularly both bradycardia (including asystole) and tachycardia (including fibrillation). This provides the significant advantage that a single device may be universally applied to treat various different dysrhythmias. Such general application leads to greater automation which has the potential for reducing the chance of applying the wrong treatment due to human error, particularly when the treatment is applied by unskilled persons. In a device capable of treating different types of dysrhythmia, desirably, the control circuit is arranged to control the impact

mechanism to change the energy of the external impact in response to the type of arrhythmia detected. For example, the range of energy levels for each form of arrhythmia and/or the detection mode may be user-calibrated to allow patient-specification.

Preferably, the impact mechanism is controllable to vary the energy of the external impact and the control circuit is arranged to control the energy of the external impact.

The advantage of varying the energy is that the effectiveness of the treatment can be improved. For example, the preferred energy ranges quoted above are fairly broad and the actual optimal energy will vary from patient to patient. Varying the energy allows optimisation of treatment for a given patient. Preferably, the energy of the external impact is controlled so as to optimise effect with minimal stimulation energy. For example, the energy may be adjusted upwards from a starting point until the desired biological affect is achieved, to strike the best possible compromise between avoidance of any damage to pre-cordial tissue structures and achievement of the desired electrophysiological response of the heart.

Also, the energy may be varied in response to the outcome of a preceding stimulation. For example, the energy may be increased if one or more of the preceding stimulations are unsuccessful.

Similarly, the energy may be varied based on the actual displacement of the sensor. To achieve this, one possible arrangement is that the impact mechanism comprises a plunger arrangement movable to deliver said external impact, and the device further comprises an optical sensor for detecting the displacement of the plunger arrangement relative to the static portion, the detected displacement being representative of the applied force and the control circuit is arranged to control the energy of the external impact in response to the detected displacement of at least one preceding impact.

The actual force imparted on the patient is a function of the deceleration characteristics of the movable plunger, and will vary from patient to patient, depending on chest compliance and soft tissue buffering, for example affected by the

amount of subcutaneous fat tissue. Thus, deceleration characteristics affect the applied force, the pressure of mechanical stimulation, and the actual work conducted on the chest. Thus the detected displacement may be used to limit tissue damage, perform patient-specific calibration, and/or to optimize other parameters, such as travel limitation or active retraction.

Pre-impact kinetic energy can be varied by either changing the mass of the plunger arrangement, or its pre-impact speed. Various mechanical arrangements are capable of achieving this. For example, the mass of the plunger arrangement could be changed by selective use of plural plungers or by by attachment of impact surface plates of varying mass. Pre-impact speed can be changed by control of the acceleration of the plunger arrangement and/or the pre-impact travel. Acceleration may be controlled by the engagement of selected multiple springs or by variation of pneumatic forces applied to the plunger, and pre-impact travel may be adjusted by an appropriate mechanism in the device.

In view of the above comments, it is envisaged that the device in accordance with the present invention might be applicable in the following situations, although these are not exhaustive. The device might be applied generally to a large proportion of patients in a cardiac or emergency ward, perhaps including the categories of patients who are currently fitted with heart rate monitors alone. The device might also be useful as a support system for patients in transit, for example in an ambulance. Furthermore, the device might be used as a preventative measure for defined risk groups (for example Stokes-Adams syndrome patients) in their own home environment, or those who are waiting for reprogramming/replacement of malfunctioning implanted rhythm management devices.

The device in accordance with the present invention offers particular advantage over the current devices for electrical stimulation such as external defibrillators, as follows. Perhaps the most significant advantage is that the mechanical devices apply an impact of an energy significantly lower than the energy applied during electrical stimulation which, as mentioned above, must be high in order to capture the entire myocardium. For example, in the case of treatment of VT

or VF, known cardioversion devices external apply shock with an energy yield of 200 joules or more. In contrast, it is expected that devices in accordance with the present invention will be effective when applying an external impact having an energy of at most 20 joules, probably in the range 4 to 12 joules.

Use of a lower energy has several distinct advantages. One advantage is to subject the patient to a lower degree of trauma. Apart from being more comfortable to the patient, this is expected to provide significant medical advantages, as there is would be no need to wait until the patient has lost consciousness (as in the case of external electrical defibrillation), before cardioversion may be initiated. This is highly significant as it reduces response times and as it allows to treat dysrhythmias at an earlier stage during their development, which is know to be a strong positive predictor of success.

Another advantage of a relatively low energy requirement is that the device may have a significantly smaller power unit. In particular, this allows the use of smaller batteries making the device significantly more portable. Improving portability is a significant advantage, because it increases the number of situations where the device may be applied and the speed of intervention as a critical factor in survival rates for cardiac arrest. It also predestines the device for preventive use as it supports patient mobility. Further advantages arise from reduced effort and cost of device maintenance

A further advantage of the present invention is that its mechanical, rather than electrical, energy delivery unit eliminates risk of electrocution for medical personnel and the patient, because the need for external electrodes to apply a high energy electric shock is avoided. The required electrical circuits may be safely packaged within the device. This also reduces the amount of servicing and checking required over long-term use of the device, and makes it more easily adaptable to settings where high ambient humidity could pose a health hazard.

The reduced chance of electrocution also makes it easier to safely apply the device in an automated mode without supervision. This in turn will significantly reduce the response times of a cardiac rhythm disturbance, which has a significant

effect on the chance of survival. For example there is the possibility of use of the device as a preventative measure in patients at risk of VT, or its deterioration into VF, in which case the present invention might prevent the development of a more serious, potentially lethal dysrhythmia.

By providing effective treatment of both brady- and tachycardias, there is the potential for preventing the loss of consciousness in asystole and reducing the instance of a VF which is fatal if untreated.

Another advantage is that the device can safely be used on patients with implanted electrical devices, such as pacemakers or ICDs, which are becoming ever more common. In contrast, use of an external electrical defibrillator device tends to disrupt the proper operation of such implanted devices, which then have to be extracted (often presenting a high-risk operation) and replaced. In contrast, inefficient or malfunctioning implanted electronic circuitry can be repaired/reprogrammed after mechanical cardioversion in the same way as before.

Use of a device in accordance with the present invention would offer significant advantages over a manually applied chest thump. A major advantage is the ability to provide continuous unsupervised application due to the automation. This greatly increases the range of circumstances in which the treatment may be applied, and the speed of delivery. Delivery of an impact by a device also allows the energy levels of the impact to be controlled, thereby reducing the risk of too small (inefficient) or too large impacts (that potentially could cause rib fractures or other tissue damage).

Some advantageous constructional features are as follows.

Advantageously, in one type of device the impact mechanism comprises:

a plunger arrangement movable to deliver said external impact; and

a resilient loading arrangement, for example a spring arrangement, for loading the plunger arrangement to drive its movement.

The advantages of using a resilient loading arrangement include low cost, portability and independence of external power supplies, so that the plunger could even be manually re-loaded, thereby providing a low energy consumption alternative

for use in the developing world.

Desirably, the impact mechanism comprises a catch mechanism for catching the plunger arrangement and releasing the plunger arrangement under the control of said control circuit. Such a catch mechanism allows for accurate control of plunger release and operational safety of the device.

Advantageously, in another type of device impact mechanism comprises:

a plunger arrangement movable to deliver said external impact; and

a pneumatic drive arrangement for driving movement of the plunger arrangement.

The advantages using a pneumatic drive arrangement are as follows. Firstly, it provides inherent uncoupling of the plunger and housing. Secondly, it could be used for repeated impacts in the absence of external power supplies by use of (miniature) compressed gas cylinders. Thus, a compressed gas implementation would allow for miniaturisation of the device, in particular in the direction of the axis of plunger movement, particularly as compared to a spring arrangement which would require a longer pathway.

Desirably, the impact mechanism comprises a catch mechanism for catching the plunger arrangement and releasing the plunger arrangement under the control of said control circuit. Such a catch mechanism allows for accurate control of plunger release and operational safety of the device.

Advantageously, the impact mechanism comprises a drive arrangement for driving movement of the plunger arrangement, the drive arrangement being arranged to uncouple the plunger arrangement prior to impact.

Such an uncoupling provides the advantage of reducing backlash and force transfer to the device upon impact. This protects the device and in particular limits damage to the electronic control circuitry.

Advantageously, the impact mechanism allows the contact area of the external impact to be varied.

It has been appreciated that impact area is an important determinant of the biological effect of a precordial impact. Firstly, the impact contact area determines

the peak pressures generated at any given impact strength, and it is therefore an important variable in reducing superficial tissue damage. Secondly, the optimal impact contact area varies with patient size. For example it is of the order of the width of two fingers for infants or of a fist-size for adults. It is therefore important to be able to change this parameter to make the device more universally applicable.

In one type of device, the impact mechanism is controllable to vary the contact area of the external impact, for example by use of a plunger arrangement comprising a plurality of plungers movable in parallel and being selectively operable to vary the contact area used to deliver the impact.

Such an impact mechanism provides the option of changing the impact contact area without detaching the device from an individual patient. This is beneficial in identifying the optimal impact characteristics for any given patient.

In another type of device, the the impact mechanism includes a plunger arrangement including an attachment portion for selectively attaching at least one impact surface plate for delivery of the impact. This allows the impact contact area to be varied by selection of the impact surface plate or plates with a desired contact area. For example, the attachment portion may allow attachment of plural impact surface plates, allowing the area to be varied by variation of the number of impact surface plates attached. Alternatively, the attachment portion can selectively receive one of a plurality of impact surface plates having different contact areas. The device maybe supplied with a set of surface impact plates for selective attachment.

Advantageously, the impact mechanism comprises:

a plunger arrangement movable to deliver said external impact; and

a travel limiter for limiting the maximum travel of the plunger arrangement.

Such a travel limiter can advantageously control tissue deformation under the impact surface and thereby limiting damage to the tissue and avoiding trauma of deeper structures, such as bones and cartilage.

Advantageously, the impact mechanism comprises:

a plunger arrangement movable to deliver said external impact; and

a drive arrangement operable to drive movement of the plunger arrangement

both to deliver said impact; and

an active retraction mechanism arranged to actively retract the plunger arrangement so as to shape the form of the external impact.

Such shaping of the form of the impact is made possible by the retraction occurring within the timescale of the impact. It allows the provision of an 'impulse-like' mechanical stimulus, which is understood to be advantageous in terms of avoidance of tissue damage and achievement of the desired biological response (that is the electrical excitation of repolarised cardiac tissue). Active retraction also allows for multiple impacts at precisely timed intervals, for example to provide pacing for asystole and bradycardia or overdrive pacing for ventricular tachycardia.

Preferably, the housing has straps for holding the unit on the chest of the patient, the straps having a pre-tensioning arrangement.

Such a pre-tensioning arrangement provides intimate mechanical coupling of the device to the chest of the patient on delivery of an impact, without which grading and reproducibility of mechanical impact properties would be impaired. At the same time, the ability to relax the harness that holds the device in place while not in acute action allows one to reduce the mechanical load on the patient during normal periods between impacts. This is essential as the device should be usable both as a means of prophylactic prevention and for prolonged periods of time, for example overnight, where a tight harness would be uncomfortable and potentially detrimental to vital functions such as breathing.

Preferably, an external impact should be delivered at a precisely defined moment during the cardiac cycle, which is difficult, if not impossible, by hand. The device would identify the optimal impact timing, for example by synchronising the mechanical stimulation to coincide with an R-wave of the ECG signal during tachycardia. This may be achieved by the intervention determination circuit outputting the trigger signal synchronised with the R-wave of the ECG signal. Similar technology for the identification of optimal stimulation timing is conventional for cardiac monitors in known ICDs.

The timing of the impact is of importance for the success of the intervention.

In general, the effectiveness of the mechanical stimulation varies depending on the character of the dysrhythmia. Considering VT, it has been shown that synchronising mechanical stimulation with the R-wave of the ECG increases the success rate of mechanical conversion. Thus, it is an advantage of the device of the present invention that the impact may be easily synchronised the cardiac cycle.

To allow better understanding, a device which is an embodiment of the present invention will now be described by way of non-limitative example, with reference to the accompanying drawing in which:

Fig. 1 is a cross-sectional view of a first cardiac stimulation device;

Fig. 2 is a detached view of the energy transmission assembly for the plunger arrangement of the device of Fig. 1;

Fig. 3 is a detailed view of an alternative energy transmission assembly for the plunger arrangement of the device of Fig. 1;

Fig. 4 is a cross-sectional view of a second cardiac stimulation device;

Fig. 5 is a cross-sectional view of a third cardiac stimulation device;

Fig. 6 is a view of the device positioned on the chest of a patient; and

Fig. 7 is a a detailed view of an alternative active retraction arrangement for the plunger arrangement of any of the devices of Figs. 1, 4 or 5.

The first cardiac stimulation device is illustrated in Fig. 1 and comprises a housing 1 having a base 1a that is covered by a replaceable, flexible membrane 5 for sealing the device. The membrane 5 is mounted on a metal ring 5a which is screwed on the main housing 1. The membrane 5 is disposable and can be removed and replaced. For use of the device, the housing 1 is arranged in a precordial position on the chest of a patient 4 with the base 1a of the housing 1 and membrane 5 facing the patient 4, as shown in Figs. 1 and 6. Preferably, the housing 1 is positioned to be in the area of "absolute dullness", as established using percussion of the heart (roughly between the left sternal border, at the level of the bottom edge of the fourth rib, extending to about 2.3cm medial of the left mid-clavicular line).

The device is fixed in place by straps 15 attached to the housing 1, which form a harness around the patient 4 for stable positioning. The straps 15 include a

pre-tensioning mechanism 16 arranged to provide intimate mechanical coupling of the device to the chest of the patient 4 on delivery of an impact, whilst reducing the mechanical load on the patient 4 during normal periods between impacts. The straps 15 may also contain routing for external input/output functions or electrodes of the control circuit described in more detail below. The straps 15 are arranged to form a harness that allows access to areas on the chest of the patient 4 that would be used for placement of electrodes for an external electrical cardioversion device, if necessary. A built-in safety mechanism inactivates the device during current surges such as associated with electrical defibrillation.

Mounted inside the housing 1 is an impact mechanism arranged to deliver an external impact to the chest of the patient 4 through the base 1a of the housing1. The impact mechanism is arranged as follows.

The impact mechanism has a plunger arrangement 2 including a plunger 2a slidably mounted on a rod 2b made of metal and covered with Teflon or any other suitable material to reduce friction. The plunger 2a has a predetermined mass.

The plunger arrangement 2 further includes an energy transmission assembly 8 which, as shown in detail in Fig. 3, comprises a block 8a mounted in an aperture 1b in the base 1a of the housing 1 to be movable towards the patient 4. The block 8a has a head 8b in a position to be impacted by the plunger 2a. The block further has an attachment portion 8c to which a surface impact plate 29 can be removably attached. The surface impact plate 29 faces the membrane 5 and so impacts the chest of the patient 4 when the block 8a is moved by an impact from the plunger 2a.

The surface impact plate 29 can be replaced and exchanged for a different plate 29 with a different contact area. This allows for modification of the pressure applied to the patient's body. It is also possible to change the profile of the plate to be (concave or flat). In practice, the device may be supplied with a set of different plates 29 for selective attachment.

A set of adjustable screws 31 mounted in the base 1a of the housing 1 act as a travel limiter to limit travel of the impact plate 29. This allows control of deceleration properties.

The energy transmission assembly 8 includes a spring 30, for example a semi-flat circular spring, which is mounted to the base 1a of the housing 1 and engages the block 8a to actively withdraw the surface impact plate 29. Therefore, the spring 30 acts as an active retraction arrangement which allows the form of the impact to be shaped.

An alternative form of the energy transmission assembly 8 is illustrated in Fig. 3. This additionally comprises a set of auxiliary plates 32 mounted on flexible spokes 34 that are connected to a stepping or linear motor 33. The auxiliary plates 32 come into position by rotation under impact surface plate 29 and above the elastic membrane 5. The set of plates 32 is mounted on a set of flexible arms 34 that is connected to the shaft of a small electrical motor 33. The motor 33 is assembled to the main housing 1. The energy delivered by the moving mass 2 is transmitted to the selected plate 34 by the metal plate 29 located above. Several plates 32 can be accommodated through the used of such an arrangement. This arrangement allows the changing of the impact contact area by a rotation of the motor axis without detaching the device from an individual patient.

The device has a catch mechanism 3 mounted in the housing 1 and arranged to catch and release the plunger arrangement 2. The catch mechanism 3 comprises a pin 3b releasbly engaged in a hole 3a formed in the plunger 2a. The hole 3a is machined as a groove extending around part of the side of the block to avoid any difficulty with orientation or alignment of the plunger 2a . The pin 3b is activated in both directions in and out of the hole 3a using a magnetic actuator 24.

As a safety measure, the catch mechanism 3 may also be arranged to prevent delivery of an impact in the absence of an electrical power supply to the control circuit

The device has a spring 6 under compression between the housing 1 and the plunger 2a to act as a drive arrangement for driving the plunger arrangement 2 to deliver a controlled mechanical impact to the patient 4. The spring 6 is mounted to the housing 1.

As an alternative, the spring 6 may be replaced by a more complicated spring

arrangement, for example an array of high power springs with variable stiffness which are selectively engagable to vary the energy applied by the device. Alternatively, the spring 6 may be replaced by other resilient energy storage means, or indeed by some other form of mechanism including, but not restricted to, magnetic, mechanic or pneumatic drives. Examples of alternative drive arrangements are a solenoid, electrically driven motor, gearing system or compressed air reservoir.

The magnetic actuator 24 and pin 3b are movable along a direction parallel to the rod 2a of the plunger arrangement 2 using a stepping motor 7. This permits modification of the pre-impact travel of the plunger arrangement 2. This allows variation of the compression length of the spring 6 and hence variation of the energy delivered by an impact.

For post-impact re-setting of the plunger arrangement 2, the impact mechanism has a retraction mechanism 9 for retracting the previously released concentric cylinders of the plunger arrangement 2, thereby also re-loading the spring arrangement 6. In particular, the retraction mechanism 9 comprises twisted steel wires 28 attached to the plunger 2a of the plunger arrangement 2 and passing over pulleys 9a to an electric motor-gearbox assembly 22 powered by an external battery (BATT). The retraction mechanism 9 is arranged to operate at sufficient speed to allow repeated mechanical stimulation of the patient 4, at rates not exceeding 4 Hz, typically below 3 Hz, and most often between 1 and 2 Hz.

As an alternative, in order to reduce electro-magnetic field generation, the retraction mechanism 9 could comprise novel shape memory alloys (alloys and polymers that respond to low voltage input by mechanical deformation, such as shortening, while generating very large forces).

An optical sensor 3 is used to detect the displacement of the plunger 2a, and hence the force of the impact. The sensor 23 consists of two parts: a transparent disc 23a including a grating and a body 23b comprising the light source and the photon detector. The body 23b of the light sensor 23 is mounted on the main housing 1. The disc 23a is coupled to the shaft of the motor-gearbox assembly 22 so that

rotation of the motor-gearbox assembly 22 is recorded by the body 23b of the sensor 23. The sensor 23 delivers electric pulses that are proportional to the displacement of the plunger 2a. The sensor 23 gives the information required for the determination of the position of the moving plunger 2a, its speed and consequently the delivered energy. The motor-gearbox assemblies 22 are fitted with high-ratio gearboxes. Those gearboxes or part of them are mechanically uncoupled from the main motor shafts before the release of the mass to avoid loss of energy through the gearbox or motor.

The device includes a safety catch 21. This is a simple mechanical assembly that is activated manually from the outside of the housing 1 and pushes a piece of metal into the way of the plunger 2a to lock the plunger arrangement 2 and avoid accidental firing of the device.

In use, the device is loaded by operation of the retraction mechanism 9 to retract the plunger 2a to a position where it is caught by the catch mechanism 3. This position is selected by control of the stepping motor 7. When an impact is desired, the catch mechanism 3 is operated to release the plunger 2a which moves towards and impacts the head 8a of the block 8b of the energy transmission assembly 8 which in turn moves towards the patient 4 so that the surface impact plate 29 delivers the impact to the chest of the patient 4 through the membrane 5. The membrane 5 is sufficiently flexible as to not significantly affect the impact supplied by the plunger arrangement 2 while preventing abrasive and other skin lacerations of the patient 4.

The spring 6 is designed to release the plunger 2a before the plunger 2a impacts the energy transmission assembly 8. This uncouples the plunger arrangement 2a from the drive arrangement in the form of the spring 6 prior to the impact, which advantageously reduces force transmission back to the device.

The duration of the impact is typically of the order of 1ms but may have any duration up to 100 ms, preferably up to 10 ms.

The energy and force of the impact may be varied by control of any one or more of: (a) the energy delivery means, in particular by the selection of spring 6; (b) the pre-impact travel controlled by the stepping motor 7; and (c) the maximum travel

of the plunger 2a which is controlled by the adjustable screws 31.

Consequently, the impact mechanism provides for delivery of a mechanical impact having a variable energy to a precordial position on the chest of the patient 4, with variable contact area and indentation depth (controlled by the adjustable screws 31).

The above mechanisms are operated by the control circuit for impact delivery which is described in more detail below, to release the plunger arrangement 2 at a pre-determined point relative to the cardiac cycle, and hence cause operation of the impact mechanism.

The electrical circuits of the device, including the delivery control circuit will now be described in more detail. Except where references made to external components, the electrical circuits of the device are mounted in the housing 1. All circuitry is preferably based on an integrated circuit design with integral microprocessor and memory block, all mounted to the housing 1. However, the various functions could alternatively be performed by dedicated hardware.

The device has a set of contact electrodes 10 integrated into the housing 1 on the patient side of the device. The contact electrodes 10 are arranged to contact the chest of the patient 4 when the housing 1 is positioned thereon. The contact electrodes 10 are electrically connected to an ECG detection block 17 of the control circuit, which is arranged to provide an ECG signal representative of the cardiac rhythm of the patient 4 for analysis by an intervention determination block 18. The ECG block 17 correspond to conventional technology commonly used, for example, in known ICDs. Accordingly a detailed description thereof is unnecessary.

As an alternative to the integrated contact electrodes 10, the ECG block 17 of the control circuit may be connected to external connection terminals 11 in the housing 1 for provision of external signals, such as recordings from contact electrodes.

Via the same external connection terminals 11 the ECG signal recorded by the impact device may also be supplied to an external connection terminal for connection, for example, to an external monitor or other recording or staff

notification equipment, or for the display of the ECG signal.

The ECG signal is supplied to the intervention determination block 18 which is arranged to monitor and analyse the ECG signal and to output a trigger signal on determining the need for cardiac mechanical stimulation. The intervention determination block 18 is programmable via an external interface port 12, connected to the device housing 1. The intervention determination block 18 is in itself of conventional form, for example of the type used commonly in known ICDs. Accordingly, a detailed description thereof is unnecessary.

The trigger signal from the intervention determination block 18 is supplied to a impact delivery control block 19. The impact delivery control block 19 controls the mechanical simulation provided by device. The control block 19 is programmable via an external interface port 13. The primary function of the control block 19 is to output a control signal to the catch mechanism 3 to release the plunger arrangement 2, and hence cause operation of the impact mechanism.

In addition, the control block 19 determines delivery parameters to control the energy and force of the impact. The control block 19 controls the various elements of the impact mechanism in accordance with the delivery parameters, in particular the catch mechanism 3, and the pre-impact travel length 7. The control block 19 also controls the retraction mechanism 9. The control block 19 controls the catch mechanism through a PIC (plunger control) electronics block 27 and controls the motor-gear box assembly 11 of the retraction mechanism through a MoC (motor control) electronics block 25.

The control block 19 also receives signals from the optical sensor 23 through an OpC (optical sensor control) electronics block 26. The control block 19 may be arranged to vary the parameters of an impact, in particular the energy, in response to the displacement of at least one previous impact detached by the optical sensor 23.

If, for example, mechanical stimulation is to be synchronised with the R wave of the ECG, the ECG circuit 17 provides the timing information to the intervention determination logic 18, which feeds the impact delivery circuit 19 with the information required to release 3 a controlled impact at accurately the required

timing.

All interventions and patient data can be temporarily stored in a memory block 20 for later or instantaneous retrieval via external and input-output interface 14. The memory block also contains patient-specific information, entered via an interface 14, to specify specific parameters like age, weight, build, etc, to allow patient-adaptation of mechanical impact regimes. Via the input/output interface 14, the device may therefore be user-calibrated.

The same external ports 12, 13 and 14 also allow, as an alternative, accessing and applying external control circuitry to replace or override all or part of the internal control circuits.

This input/output interface 14 may take any suitable form. For example, it may be a key pad and display integrated into the housing 1 or attached to the straps 15 of the device. Alternatively, it may be a data port for connection to an external unit, in which case routes for data transfer may be integrated into the strap 15 or accessible directly form the device housing 1.

The input/output device 14 may be used to change program settings of the control circuitry to operate in different modes for the treatment of different dysrhythmias.

For example, in a first mode, the control circuit may control the device to operate during VT, for example over and above a patient-specific range of heart rates. In this mode, the intervention determination block 18 outputs a trigger signal on determination of the need for stimulation during VT and the delivery control block 19 causes operation of controlled mechanical stimulation in response thereto.

The control block 19 selects delivery parameters an external impact with a defined energy, usually from 5 to 15 joules. Energy levels will normally be set to be minimal, within the above range, at the beginning, and – if mechanical impact delivery did not result in cardioversion, the impact energy will be successively increased, according to a user-definable function. This self-calibration of the device can be according to a number of different algorithms for increasing the energy. For example, the energy may be increased successively in either a linear, non-linear, or

pre-determined stepped manner. Alternatively, the energy may be increased as a function of recorded or applied parameters, such as taking into account any ECG changes caused by the preceding impact (even though the impact did not complete cardioversion). Alternatively, the self-calibration may take into account monitoring of the timing and interval between subsequent trigger signals. Upon determination of successful cardioversion, the applied energy level will stored in the memory block 20 and used as a reference for further use.

In a second mode, the control circuit may be arranged to cause operation only upon detection of during VF. In this mode, the intervention determination 18 outputs a trigger signal on detecting need for stimulation during VF and the delivery control block 18 causes operation in response thereto. In the second mode, the control block 19 controls the delivery parameters to deliver an impact, typically with an energy from 10 to 25 joules. Energy levels will normally be set to be minimal, within the above range, at the beginning, and – if mechanical impact delivery did not result in cardioversion, self-calibration ensures as described above.

In a third mode, the device is arranged to treat bradycardia or asystole. In this mode, the intervention determination logic 18 outputs a trigger signal on detection of need for extra stimulation during bradycardia or asystole and the delivery control block 19 issues appropriate control signals in response thereto. In this mode, the control block 19 controls the delivery parameters to deliver an impact, typically with an energy between 0.01 and 5 joules, often below 1 Joule. Energy levels will normally be set to be minimal, within the above range, at the beginning, and – if mechanical impact delivery did not result in cardioversion, self-calibration ensues as described above.

A fourth mode is to allow any combination of the above modes, for example to explicitly combine VT and VF modes, or to allow all three. The fourth mode is the default mode of operation.

The electrical circuitry of the device is powered by an external battery BATT which may be mounted, for example, on the straps 15, or independent power supply routed via the straps 15. Alternatively an internal battery could be used.

There will now be described some further cardiac stimulation devices which are modified versions of the first cardiac stimulation device and share many identical elements. Only the modifications will be described. For the common elements, the same reference numerals will be used and a description thereof will not be repeated.

A second cardiac stimulation device is shown in Fig. 4 and is a simple low-cost device working without electric power. The main principle is similar to the first device described by Fig. 1 in that it uses a spring 6. However, the spring 6 is compressed manually through the use of a crank 35 coupled to a set of gearwheels (pinions) 36 to 38 that activate a couple of ratchet controlled winding wheels 39. These winding wheels allow the compression of the spring 6 through the twisted steer wire 28. A manually activated ratchet control assembly 40 unlocks the wheels and allows the propulsion of the mass 2 through the force exerted by the compressed spring 6. On the side of the housing 1 there is a graduated scale 52 to adjust the energy of the system. A small metal rod 53 is mounted on the mass 2 to play the role of the marker for the scale 52.

Thus the electrical circuits are omitted in the second cardiac stimulation device. Alternatively, the second device could be controlled by the same circuit as the first cardiac stimulation device.

A third cardiac stimulation device is shown in Fig. 5 in which the drive arrangement of the first device in the form of the spring 6 is replaced by a pneumatic drive arrangement arranged as follows. In particular, the pneumatic drive arrangement comprises a small container 43 of carbon dioxyde or compressed air or any other compressed gas compatible with the safety requirements for the environment. The container 43 supplies high pressure gas to a main cylinder 46 through a pressure regulator 43 and a high-speed electro-mechanical value 44. A piston 49 is fitted with an O-ring seal 48 to avoid loss of pressure in the high pressure chamber of the main cylinder 46. An electro-mechanical plunger 50 holds the piston in "armed" position before the moving part of the plunger is retracted to allow the firing of the piston 49. Operation of the plunger 50 allows th piston 49 to move in the main cylinder 46 where it acts as a plunger in the same manner as the plunger 2a of

the first device. After the impact, the piston 49 comes back automatically due to the action of a spring 47 connected between the piston 49 and the housing 1. The main cylinder 49 has an exhaust channel to bring the pressure in the main cylinder 49 to atmospheric pressure The delivered energy is adjusted by a combined effect of pressure regulator 43 and the initial gas volume delivery regulated by the fast valve 44. Energy measurement is done by a measurement of the speed of the piston towards the end of the gun 46 where two sets of light sensors 51 allow determination of the speed of the piston.

Fig. 7 shows an active retraction system which may optionally be incorporated in any of the devices and which comprises a set of electro-magnetic actuators 58 arranged symmetrically. There may be 2 or preferably 4 electro-magnetic actuators 58. The electro-magnetic actuators 58 actuate movable arms 59 which are connected to the head 8a of the energy transmission assembly 8 through spring-like metal pieces 60. The actuators 58 are connected to the housing 1 through a ball-bearing mounted axis 57 and a plate 56. The actuators 58 are operated to provide active retraction of the block 8b to shape the form of the impact. The system includes an optical sensor 61 that can be adjusted in height to activate the set of electro-magnetic actuators 58 with the adequate timing relative to the impact time. The vertical position of the optical sensor 61 can be mechanically adjusted to achieve perfect timing synchronisation between the impact delivery and the retraction.

Claims

1. A cardiac stimulation device for treating dysrhythmia of the heart of a patient by mechanical energy delivery, comprising:

a housing for disposition in a precordial position on the chest of the patient, the housing having an impact mechanism arranged to deliver an external impact to the chest with an energy capable of stimulating electrical excitation and consequent contraction of the heart of the patient;

a cardiac monitor comprising an intervention determination circuit arranged to monitor an ECG signal representative of the rhythm of the heart of the patient and output a trigger signal indicative of a need for stimulation of the heart;

a control circuit arranged to cause operation of the impact mechanism in response to the trigger signal output by the intervention determination circuit.

2. A cardiac stimulation device according to claim 1, wherein the intervention determination circuit is arranged to output a trigger signal indicative of a need for stimulation of the heart during ventricular tachycardia.

3. A cardiac stimulation device according to claim 2, wherein the impact mechanism is arranged to deliver an external impact with an energy of from 1 to 10 joules, preferably from 3 to 8 joules.

4. A cardiac stimulation device according to any one of the preceding claims, wherein the intervention determination circuit is arranged to output a trigger signal indicative of a need for stimulation of the heart during ventricular fibrillation.

5. A cardiac stimulation device according to claim 4, wherein the impact mechanism is arranged to deliver an external impact with an energy of from 1.5 to 15 joules, preferably from 4 to 12 joules, or more preferably from 6 to 10 joules.

6. A cardiac stimulation device according to any one of the preceding claims, wherein the intervention determination circuit is arranged to output a trigger signal indicative of a need for stimulation of the heart during bradycardia or asystole.

7. A cardiac stimulation device according to claim 6, wherein the impact mechanism is arranged to deliver an external impact with an energy of from 0.01 to 5 joules.

8. A cardiac stimulation device according to any one of the preceding claims, wherein the trigger signal is synchronised relative to the cardiac cycle and the control circuit is arranged to cause operation of the impact mechanism in synchronism with the trigger signal.

9. A cardiac stimulation device according to claim 8, wherein the trigger signal is synchronised with the R-wave of the ECG signal.

10. A cardiac stimulation device according to any one of the preceding claims, wherein the impact mechanism is controllable to vary the energy of the external impact.

11. A cardiac stimulation device according to claim 10, wherein the control circuit is arranged to control the impact mechanism to change the energy of the external impact in response to the type of arrhythmia detected.

12. A cardiac stimulation device according to claim 11, wherein the range of energy levels for each form of arrhythmia and the detection mode are user-calibrated to allow patient-specification.

13. A cardiac stimulation device according to any one of the preceding claims, wherein the impact mechanism is controllable to vary the energy of the external

impact and the control circuit is arranged to control the energy of the external impact.

14. A cardiac stimulation device according to claim 13, wherein the control circuit is arranged to control the energy of the external impact in response to the outcome of a preceding stimulation

15. A cardiac stimulation device according to claim 14, wherein the control circuit is arranged to control the energy of the external impact so as to optimise effect with minimal stimulation energy.

16. A cardiac stimulation device according to claim 13, further comprising an optical sensor for detecting the displacement of the plunger arrangement relative to the static portion, the detected displacement being representative of the applied force and the control circuit being arranged to control the energy of the external impact in response to the detected displacement of at least one preceding impact.

17. A cardiac stimulation device according to claim 16, wherein the optical sensor is fixed to the static portion, and an optical grating is coupled to the moveable plunger to allow the optical sensor to detect the displacement of the plunger arrangement relative to the static portion.

18. A cardiac stimulation device according to any one of the preceding claims, wherein the impact mechanism is arranged to deliver an external impact having a duration of at most 100 ms.

19. A cardiac stimulation device according to any one of the preceding claims, wherein the impact mechanism is arranged to deliver an external impact having a duration of at most 10 ms.

20. A cardiac stimulation device according to any one of the preceding claims,

wherein the impact mechanism includes a plunger arrangement movable to deliver the impact.

21. A cardiac stimulation device according to claim 20, wherein the impact mechanism further comprises a resilient loading arrangement for loading the plunger arrangement to drive its movement.

22. A cardiac stimulation device according to claim 21, wherein the resilient loading arrangement is a spring arrangement.

23. A cardiac stimulation device according to claim 21 or 22, wherein the impact mechanism comprises a catch mechanism for catching the plunger arrangement and releasing the plunger arrangement under the control of said control circuit.

24. A cardiac stimulation device according to claim 20, wherein the impact mechanism further comprises a pneumatic drive arrangement for driving movement of the plunger arrangement.

25. A cardiac stimulation device according to claim 24, wherein the impact mechanism comprises further comprises a catch mechanism for catching the plunger arrangement and releasing the plunger arrangement under the control of said control circuit.

26. A cardiac stimulation device according to any one of claims 20 to 25, wherein the impact mechanism comprises a drive arrangement for driving movement of the plunger arrangement, the drive arrangement being arranged to uncouple the force applied by the drive arrangement from the plunger arrangement prior to impact.

27. A cardiac stimulation device according to any one of the preceding claims, wherein the impact mechanism is controllable to vary the force of the external

impact.

28. A cardiac stimulation device according to any one of claims 20 to 27, wherein the impact mechanism includes an arrangement for varying the pre-impact travel of the plunger arrangement.

29. A cardiac stimulation device according to any one of claims 20 to 28, wherein the impact mechanism further comprises a travel limiter for limiting the maximum travel of the plunger arrangement.

30. A cardiac stimulation device according to any one of claims 20 to 29, wherein the impact mechanism further comprises:

a drive arrangement operable to drive movement of the plunger arrangement to deliver said impact; and

an active retraction arrangement arranged to actively retract the plunger arrangement so as to shape the form of the external impact.

31. A cardiac stimulation device according to any one of claims 20 or 26 to 30, wherein the impact mechanism further comprises:

a drive arrangement operable to drive movement of the plunger arrangement to deliver said impact; and

a catch mechanism for catching and releasing the plunger arrangement under the control of the control circuit.

32. A cardiac stimulation device according to any one of the preceding claims, wherein the impact mechanism allows the contact area of the external impact to be varied.

33. A cardiac stimulation device according to claim 32, wherein the impact mechanism includes a plunger arrangement including an attachment portion for

selectively attaching at least one impact surface plate for delivery of the impact.

34. A cardiac stimulation device according to any one of the preceding claims, wherein the housing has straps for holding the unit on the chest of the patient, the straps having a pre-tensioning arrangement.

35. A cardiac stimulation device according to any one of the preceding claims, wherein the cardiac monitor further comprises an ECG circuit for producing the ECG signal.

Fig.1.

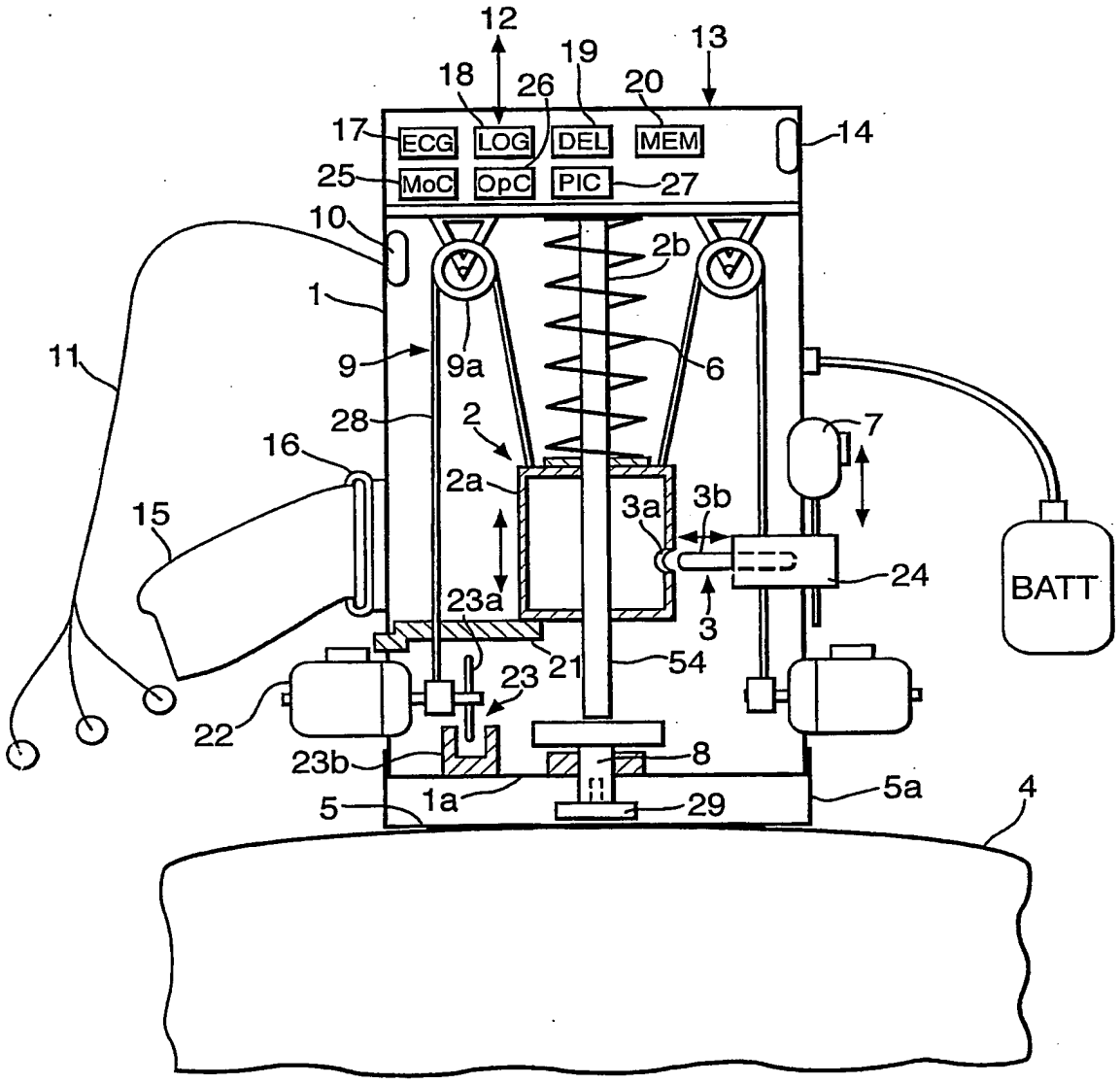
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Fig.2.

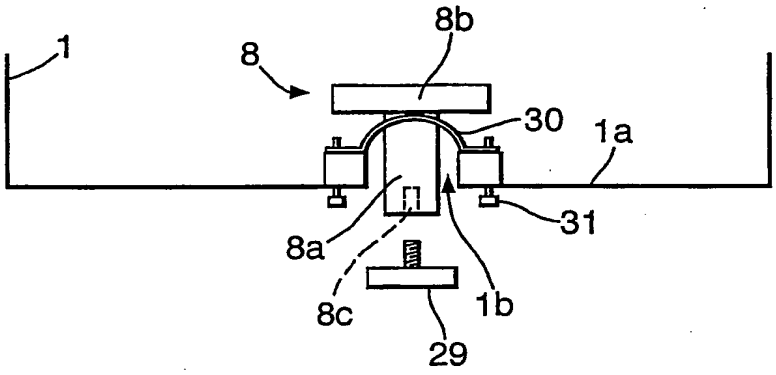

Fig.3.

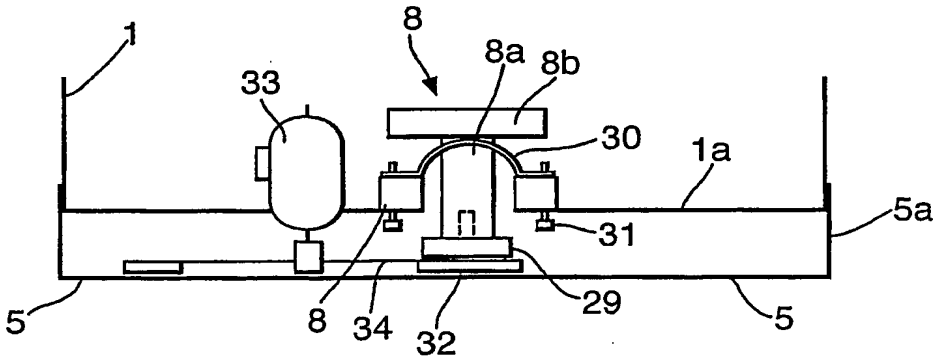

Fig.4.

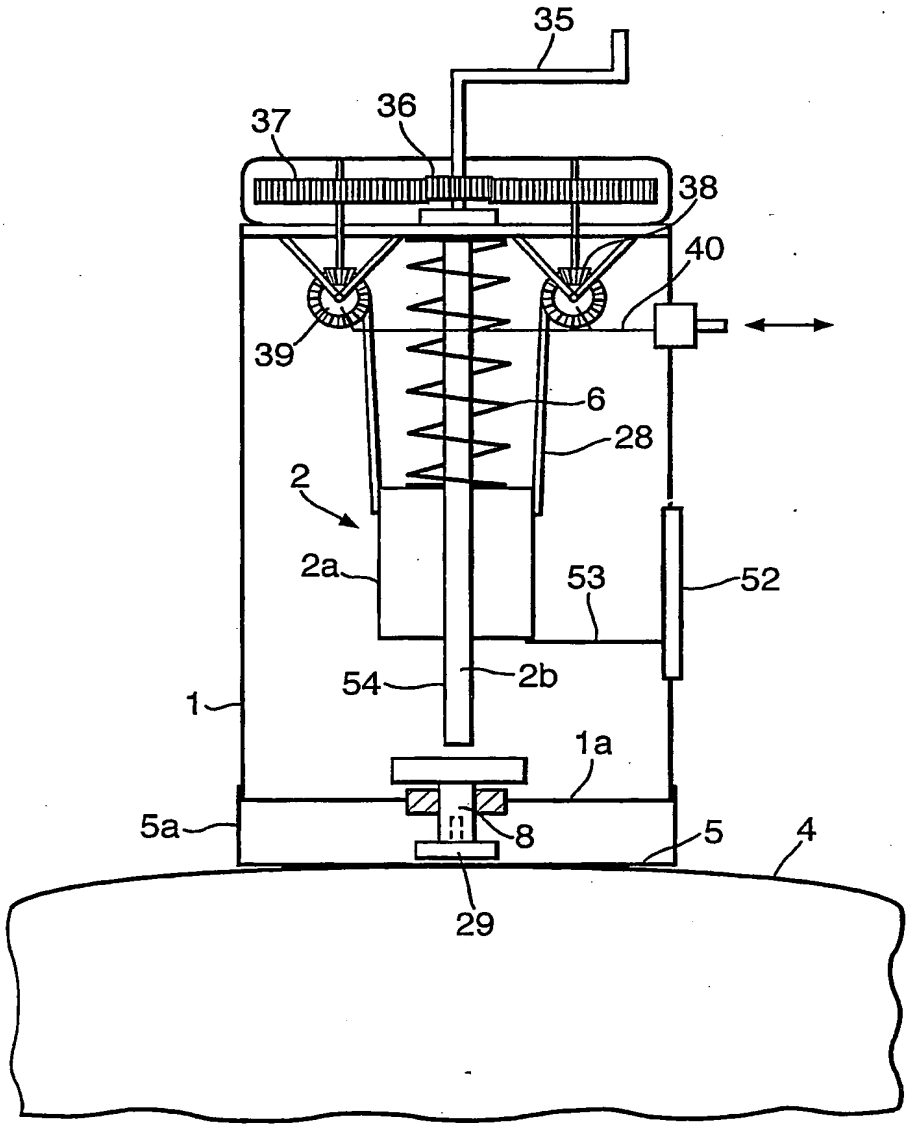

Fig.5.

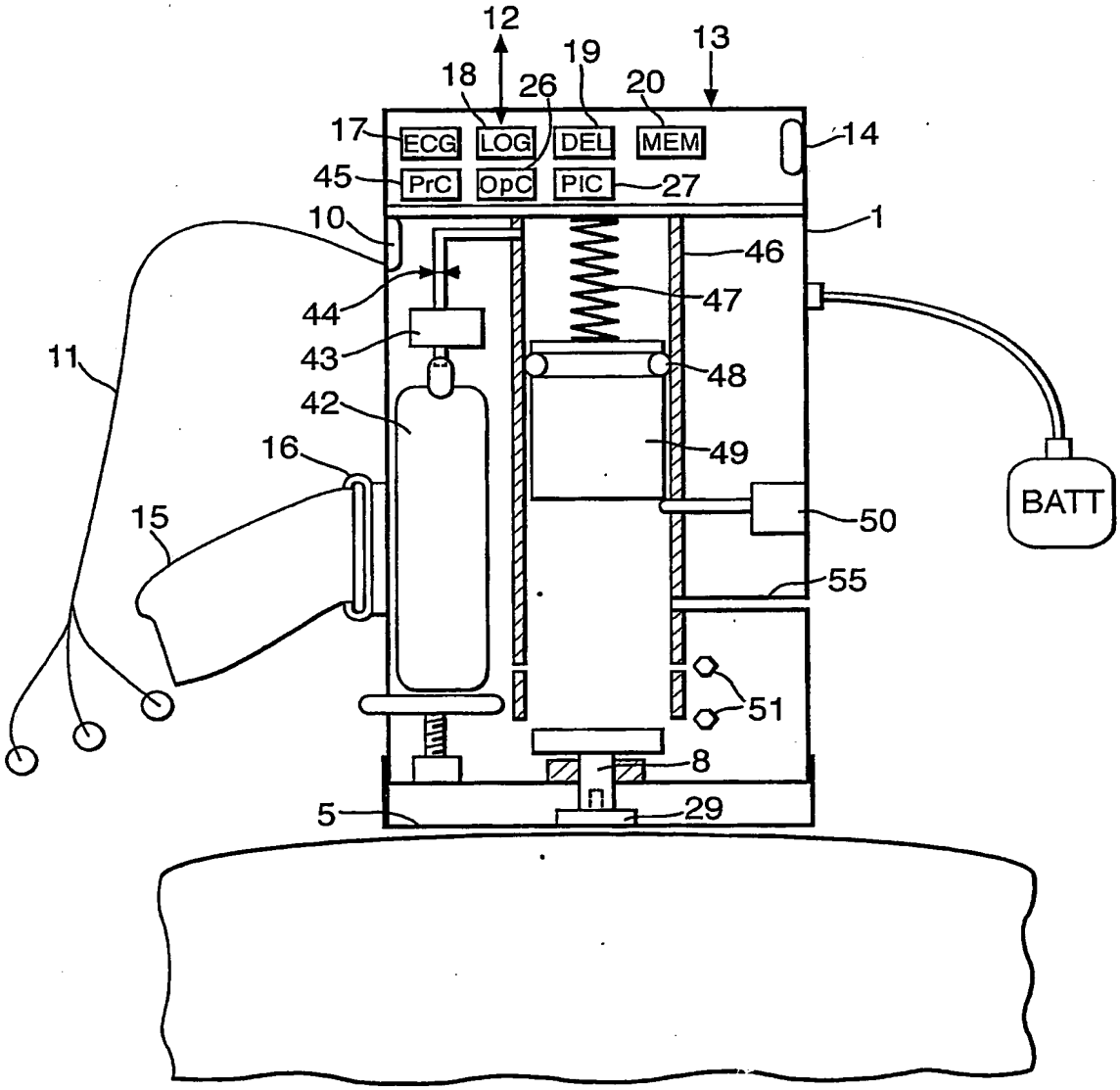
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Fig.6.

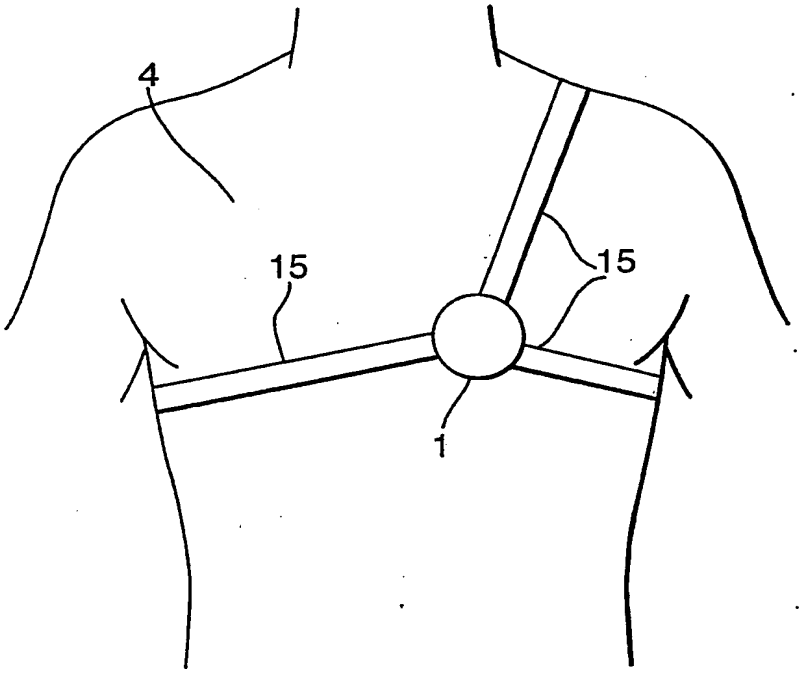
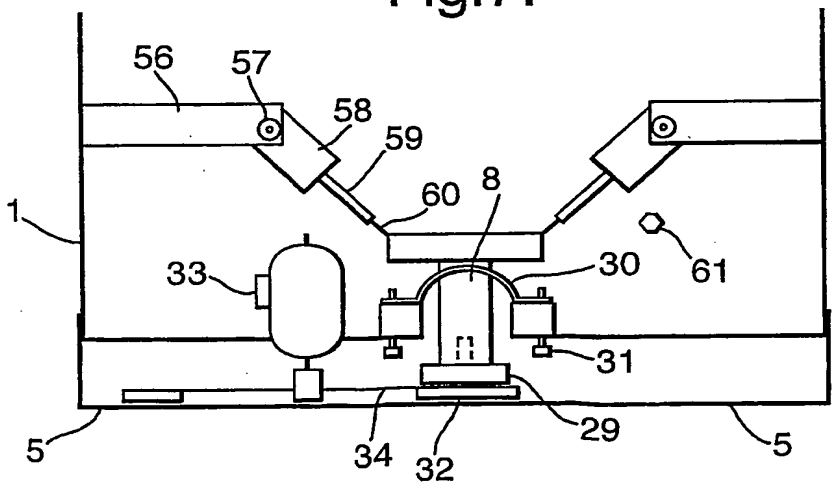


Fig.7.



INTERNATIONAL SEARCH REPORT

Ir tional Application No
PCT/GB2004/000342

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61H31/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61H

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, PAJ, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 265 228 A (ZOLL PAUL M) 5 May 1981 (1981-05-05) the whole document ---	1-10,15, 20,21, 29,30, 32,33,35
X	US 6 171 267 B1 (BALDWIN II R MITCHELL) 9 January 2001 (2001-01-09) the whole document ---	1,8,10, 14,20, 24, 27-30,35
L	US 5 683 424 A (DZWONCZYK ROGER R ET AL) 4 November 1997 (1997-11-04) incorporated by reference in US6171267 the whole document --- -/--	1,8,10, 14,20, 24, 27-30,35

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 June 2004	24/06/2004

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